Texas Department of Health
Bureau of Food and Drug Safety
Drugs and Medical Devices Division

TDH Web Site: http://www.tdh.state.tx.us/bfds/dmd/drugrules.html

LICENSING OF WHOLESALE DISTRIBUTORS OF DRUGS--INCLUDING GOOD MANUFACTURING PRACTICES
(25 Texas Administrative Code, §§229.251 - 229.254)

Section

§229.251 Definitions

The following words and terms, when used in these sections, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Department--Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756.

(2) Flea market--A location at which two or more booths or similar spaces are rented or otherwise made available temporarily and at which persons offer tangible personal property for sale.

(3) Manufacturer--A person who manufactures, prepares, propagates, compounds, processes, packages, repackages, or changes the container, wrapper, or labeling of any drug package.

(4) Place of business--Each location at which drugs are distributed at wholesale as defined in the Health and Safety Code, Chapter 431.

(5) Wholesale distribution--Distribution to a person other than a consumer or patient, including, but not limited to distribution to any person by a manufacturer, repacker, own label distributor, jobber, or wholesaler.

§229.252 Licensing Fee and Procedures

(a) License fee.

(1) All wholesale distributors of drugs who are not manufacturers of drugs in Texas shall obtain a license annually with the Texas Department of Health (department). Except as provided for in paragraph (2) of this subsection, wholesale distributors of drugs who are not manufacturers of drugs in Texas shall pay a non-refundable licensing fee for each place of business operated as follows:

(A) $250 per distributor engaged in distribution only of compressed medical gases (no transfilling operations) having gross annual drug sales of $0 - $20,000;

(B) $400 per wholesale distributor having gross annual drug sales of $0 - $199,999.99;

(C) $650 per wholesale distributor having gross annual drug sales of $200,000 - $19,999,999.99;

(D) $850 per wholesale distributor having gross annual drug sales greater than or equal to $20 million; and

(E) $0.00 per wholesale distributor engaged in the distribution of an over-the-counter drug by a charitable organization, as described in the Internal Revenue Code of 1986, §501(c)(3), to a nonprofit affiliate of the organization to the extent otherwise permitted by law.

(2) A wholesale distributor of drugs who is not a manufacturer of drugs, who is required to be licensed under this section and who is also required to be licensed as a device distributor under §229.439(a)(1) of this title (relating to Licensure Fees) or as a food wholesaler under §229.182(a)(3) of this title (relating to Licensing Fee and Procedures) shall pay a combined non-refundable licensing fee for each place of business. The licensing fee shall be based on the combined gross annual sales of these regulated products (foods, drugs, and/or devices) as follows:

(A) $200 for each place of business having combined gross annual sales of $0 - $199,999.99;

(B) $300 for each place of business having combined gross annual sales of $200,000 - $499,999.99;

(C) $400 for each place of business having combined gross annual sales of $500,000 - $999,999.99;

(D) $500 for each place of business having combined gross annual sales of $1 million - $9,999,999.99; and

(E) $750 for each place of business having combined gross annual sales greater than or equal to $10 million.

(3) All wholesale distributors of drugs who are manufacturers of drugs in Texas shall obtain a license annually with the department and shall pay a non-refundable licensing fee for each place of business operated as follows:

(A) $400 per wholesale distributor having gross annual drug sales of $0 - $199,999.99 (includes a compressed and/or liquid medical gas transfiller);

(B) $650 per wholesale distributor having gross annual drug sales of $200,000 - $19,999,999.99; and

(C) $850 per wholesale distributor having gross annual drug sales greater than or equal to $20 million.

(4) All out-of-state wholesale distributors of drugs who distribute drugs into the State of Texas must pay an annual non-refundable license fee as follows:

(A) $750 per out-of-state wholesale drug distributor; or

(B) $500 per out-of-state wholesale drug distributor with gross annual sales of $20 million or less, provided an outside audited statement demonstrating gross annual sales are less than $20 million is provided to the department.

(5) If the United States Food and Drug Administration (FDA) determines, with respect to a product that is a combination of a drug and a device, that the primary mode of action of the product is as a drug, a person who engages in wholesale distribution of the product is subject to licensing as described in this section.

(6) For the purpose of collecting licensing fees under this section, a person that distributes both its own manufactured drugs and drugs it does not manufacture must obtain only a wholesale distributor of drugs (manufacturing) license. However, when calculating the amount of the licensing fee, the manufacturer must include the total for all drugs manufactured and distributed from the place of business. In addition, drug warehousing locations operated by a drug distributor, including locations from which drugs are held for limited periods of time for distribution, and which are totally separate from any manufacturing location, must be individually licensed as drug distributors.

(7) A firm that has more than one business location may request a one-time prorating of fees when applying for a license for each new location. Upon approval by the department, the expiration date of the license for the new location will be the same as the expiration date of the firm's other licensed locations.

(b) License forms. Licensing forms may be obtained from the Texas Department of Health, Drugs and Medical Devices Division, 1100 West 49th Street, Austin, Texas 78756.

(c) License statement. The wholesale distributors' licensing statement shall be signed and verified by the owner, partner, president, or corporate designee, shall be made on the department furnished license form, and shall contain the following information:

(1) the legal name under which the business is conducted;

(2) the address of each place of business that is licensed;

(3) if a proprietorship, the name and residence address of the proprietor; if a partnership, the names and residence addresses of all partners; if a corporation, the date and place of incorporation and name and address of its registered agent in the state; or if any other type of association, then the names of the principals of such association;

(4) the names and residence addresses and valid driver's license of those individuals in an actual administrative capacity which, in the case of proprietorship, shall be the managing proprietor; partnership, the managing partner; corporation, the officers and directors; or those in a managerial capacity in any other type of association;

(5) for each place of business, the residence addresses of the individuals in charge thereof; and

(6) a list of categories which must be marked and adhered to in the determination and paying of the fee.

(d) Two or more places of business. If the wholesale distributor operates more than one place of business, the wholesale distributor shall license each place of business separately.

(e) Pre-licensing inspection. The applicant shall cooperate with any pre-licensing inspection by the department of the wholesale distributor's facilities. The department may accept reports from authorities in other jurisdictions to determine the extent of compliance with the minimum standards in this chapter for applicants located out-of-state.

(f) Issuance of license. The department may license a wholesale distributor of drugs who meets the requirements of this section and §229.253 of this title (relating to Minimum Standards for Licensing).

(1) The initial license shall be valid for one year from the start date of the regulated business activity which becomes the anniversary date.

(2) The renewal license shall be valid for one year from the anniversary date.

(g) Renewal of license.

(1) Each year, the wholesale distributor of drugs shall renew its license following the requirements of this section and §229.253 of this title.

(2) A person who holds a license issued by the department under the Health and Safety Code shall renew the license by filing an application for renewal on a form prescribed by the department, accompanied by the appropriate licensure fee. A licensee must file for renewal before the expiration date of the current license. A person who files a renewal application after the expiration date must pay an additional $100 as a delinquency fee.

(3) Failure to submit the renewal annually may subject the wholesale distributor of drugs to the enforcement provisions under Health and Safety Code, Chapter 431, and to the provisions of §229.254 of this title (relating to Refusal, Revocation, or Suspension of License).

(A) Amendment of license. A license that is amended, including a change of name, ownership, or a notification of a change in the location of a licensed place of business required under the Health and Safety Code, §431.206, will require submission of fees as outlined in subsection (a) of this section.

(B) Notification of change of location of place of business. Not fewer than 30 days in advance of the change, the licensee shall notify the commissioner of health (commissioner) or the commissioner's designee in writing of the licensee's intent to change the location of a licensed place of business. The notice shall include the address of the new location, and the name and residence address of the individual in charge of the business at the new location. Not more than 10 days after the completion of the change of location, the licensee shall notify the commissioner or the commissioner's designee in writing to verify the change of location, the address of the new location, and the name and residence address of the individual in charge of the business at the new address. Notice will be deemed adequate if the licensee provides the intent and verification notices to the commissioner or the commissioner's designee by certified mail, return receipt requested, mailed to the Texas Department of Health, 1100 West 49th Street, Austin.

(h) Exemption from licensing. Persons who engage in wholesale distribution of prescription drugs for use in humans are exempt from the licensing requirements of this subchapter, to the extent that it does not violate provisions of the Texas Dangerous Drug Act or the Texas Controlled Substances Act, the Health and Safety Code. The exemptions are:

(1) intracompany sales;

(2) the purchase or acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;

(3) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization, as described in the Internal Revenue Code of 1986, §501(c)(3), to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(4) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control. For the purpose of this subsection, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, contract, or otherwise;

(5) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons. For purposes of this section, "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

(6) the sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;

(7) the distribution of drug samples by manufacturers' representatives or distributors' representatives; or

(8) the sale, purchase, or trade of blood and blood components intended for transfusion.

(i) Sale of food, drugs, or devices. The provisions of this section regarding the sale of food, drugs, or devices shall be considered to include the manufacture, production, processing, packaging, exposure, offer, possession, and holding of any such article for sale; and the sale, dispensing, and giving of any such article, and the supplying or applying of any such articles in the conduct of any food, drug or device place of business.

RULE §229.253 Minimum Standards for Licensing

(a) Minimum standards. All wholesale distributors of drugs not engaged in manufacturing, processing, packing, or holding of drugs shall comply with the minimum standards specified in subsections (c) and (d) of this section as it applies to the firm's operations, and to the existing statutory standards contained in the Texas Health and Safety Code, Chapter 431. All wholesale distributors of drugs engaged in manufacturing, processing, packing, or holding of drugs shall comply with subsections (b), (c), and (d) of this section as it applies to the firm's operations, and to the existing statutory standards contained in the Texas Health and Safety Code, Chapter 431. For the purpose of this section, the policies described in the United States Food and Drug Administration's Compliance Policy Guides as they apply to drugs shall be the policies of the Texas Department of Health (department).

(b) Current good manufacturing practices in manufacturing, processing, packing, or holding of drugs by drug manufacturers.

(1) The department adopts by reference Title 21, Code of Federal Regulations, Part 210, §§210.1 - 210.3, titled "Current Good Manufacturing Practices in Manufacturing, Processing, Packing, or Holding of Drugs"; and Part 211, §§211.1 - 211.208, titled "Current Good Manufacturing Practice for Finished Pharmaceuticals" as those regulations apply to any building under the control of a drug manufacturer where drugs are manufactured, processed packaged or held.

(2) Copies are indexed and filed in the office of the Drugs and Medical Devices Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756 and are available for inspection during normal working hours.

(c) Requirements for wholesale prescription drug distributors.

(1) The department adopts by reference and will enforce Title 21, Code of Federal Regulations, Part 205, §§205.1 - 205.50, 1994, titled "Guidelines for State Licensing of Wholesale Prescription Drug Distributors", for prescription drugs.

(2) Copies are indexed and filed in the office of the Drugs and Medical Devices Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756 and are available for inspection during normal working hours.

(3) Prescription drug means any drug, human, or veterinary, required by federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to the Federal Food, Drug, and Cosmetic Act, §503(b).

(4) Legend drugs and controlled substances. A wholesale drug distributor may not possess, sell, or transfer drugs whose labels bear the legend "Caution: Federal law prohibits dispensing without a prescription" or "Rx Only" unless that person is authorized to possess, sell or transfer such drugs in compliance with the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431, Subchapter I; the Texas Controlled Substance Act, Health and Safety Code, Chapter 481; and the Texas Dangerous Drug Act, Health and Safety Code, Chapter 483.

(d) Requirements for wholesale over-the-counter drug distributors.

(1) Any building used to hold over-the-counter drugs shall be of a suitable size, construction and location to facilitate cleaning, maintenance and proper operations.

(2) Adequate lighting shall be provided in all areas.

(3) Adequate ventilation shall be provided.

(4) All over-the-counter drugs shall be held at appropriate temperatures and under appropriate conditions according to the labeling of such drugs, if applicable.

(5) Any building used in the holding of over-the-counter drug products shall be maintained in a clean and sanitary condition. Any such building shall be free of infestation by rodents, birds, insects and other vermin.

(6) Any building used in the holding of an over-the-counter drug product shall be maintained in a good state of repair.

(7) Written procedures describing the holding of over-the-counter drug products shall be established and followed and shall include:

(A) a procedure for identifying and retrieving over-the-counter drug products that are subject to a recall; and

(B) a quarantine procedure for over-the-counter drug products that have expired; are subject to recall; or are otherwise determined to be adulterated or misbranded for the return, destruction, or other disposal of those items.

(e) Buildings and facilities. No manufacturing, processing, packing or holding of drugs shall be conducted in any personal residence.

(f) Drug labeling.

(1) If a person, firm or corporation labels a drug, the label shall meet the requirements of the Texas Health and Safety Code, Chapter 431.

(2) The department adopts by reference and will enforce Title 21, Code of Federal Regulations, Part 201, §§201.1 - 201.317, titled "Labeling."

(3) Copies are indexed and filed in the office of the Drugs and Medical Devices Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756 and are available for inspection during normal working hours.

(g) Drugs general, drug advertising, specific requirements for special drugs, official names and established names, and labeling and packaging requirements for controlled substances.

(1) The department adopts by reference and will enforce Title 21, Code of Federal Regulations:

(A) Part 200, §§200.5 - 200.200, titled "General";

(B) Part 202, §202.1, titled "Prescription Drug Advertising";

(C) Part 203, §§203.1 - 203.60, titled "Prescription Drug Marketing";

(D) Part 250, §§250.10 - 250.250, titled "Special Requirements For Specific Human Drugs";

(E) Part 299, §§299.3 - 299.5, titled "Drugs; Official Names and Established Names"; and

(F) Part 1302, §§1302.01 - 1302.08, titled "Labeling and Packaging Requirements For Controlled Substances."

(2) Copies are indexed and filed in the office of the Drugs and Medical Devices Division,

Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756 and are available for inspection during normal working hours.

(h) Current good manufacturing practices in manufacturing, processing, packing, or holding of blood and blood components.

(1) The department adopts by reference and will enforce Title 21, Code of Federal Regulations, Part 606, §§606.3 - 606.170, titled "Current Good Manufacturing Practice For Blood and Blood Components."

(2) Copies are indexed and filed in the office of the Drugs and Medical Devices Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756 and are available for inspection during normal working hours.

(i) General biological products standards, standards for bacterial products, standards for viral vaccines, standards for human blood and blood products, standards for diagnostic substances for dermal test, standards for diagnostic substances for laboratory test, and standards for miscellaneous biological products.

(1) The department adopts by reference Title 21, Code of Federal Regulations:

(A) Part 600, §§600.3 - 600.15, titled "Biological Products: General";

(B) Part 610, §§610.1 - 610.65, titled "General Biological Products Standards";

(C) Part 620, §§620.1 - 620.48, titled "Additional Standards For Bacterial Products";

(D) Part 630, §§630.1 - 630.75, titled "Additional Standards For Viral Vaccines";

(E) Part 640, §§640.1 - 640.114, titled "Additional Standards for Human Blood and Blood Products";

(F) Part 650, §§650.1 - 650.15, titled "Additional Standards for Diagnostic Substances for Dermal Test";

(G) Part 660, §§660.1 - 660.105, titled "Additional Standards for Diagnostic Substances for Laboratory Test"; and

(H) Part 680, §§680.1 - 680.26, titled "Additional Standards for Miscellaneous Products."

(2) Copies are indexed and filed in the office of the Drugs and Medical Devices Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756 and are available for inspection during normal working hours.

(j) Labeling and standard requirements for the manufacturing or processing of animal biological products.

(1) The department adopts by reference and will enforce Title 9, Code of Federal Regulations, Part 113, §§113.1 - 113.455, titled "Standard Requirements."

(2) Copies are indexed and filed in the office of the Drugs and Medical Devices Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756, and are available for inspection during normal working hours.

(k) Cosmetic labeling for a person, firm, or corporation that labels a cosmetic.

(1) The department adopts by reference and will enforce Title 21, Code of Federal Regulations, Part 701, §§701.1 - 701.30, titled "Cosmetic Labeling."

(2) Copies are indexed and filed in the office of the Drugs and Medical Devices Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756 and are available for inspection during normal working hours.

(l) Cosmetics general and cosmetic product warning statement.

(1) The department adopts by reference and will enforce Title 21, Code of Federal Regulations, Part 700, §§700.3 - 700.25, titled "General"; and Part 740, §§740.1 - 740.18, titled "Cosmetic Product Warning Statements."

(2) Copies are indexed and filed in the office of the Drugs and Medical Devices Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756 and are available for inspection during normal working hours.

(m) Current good manufacturing practices in manufacturing, processing, packing, or holding of medicated feeds and Type A medicated articles.

(1) The department adopts by reference and will enforce Title 21, Code of Federal Regulations:

(A) Part 225, §§225.1 - 225.202, titled "Current Good Manufacturing Practice For Medicated Feeds"; and

(B) Part 226, §§226.1 - 226.115, titled "Current Good Manufacturing Practices For Type A medicated articles."

(2) Copies are indexed and filed in the office of the Drugs and Medical Devices Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756 and are available for inspection during normal working hours.

(n) Over-the-Counter (OTC) for human use.

(1) The department adopts by reference and will enforce Title 21, Code of Federal Regulations:

(A) Part 300, titled "General";

(B) Part 310, titled "New Drugs";

(C) Part 312, titled "Investigational New Drug Application";

(D) Part 314, titled "Applications for FDA Approval to Market a New Drug or an Antibiotic Drug";

(E) Part 316, titled "Orphan Drugs";

(F) Part 320, titled "Bioavailability and Bioequivalence Requirements";

(G) Part 329, titled "Habit-forming Drugs";

(H) Part 330, titled "Over-the-Counter (OTC) Human Drugs Which are Generally Recognized as Safe and Effective and Not Misbranded";

(I) Part 331, titled "Antacid Products for Over-the-Counter (OTC) Human Use";

(J) Part 332, titled "Antiflatulent Products for Over-the-Counter (OTC) Human Use";

(K) Part 333, titled "Topical Antimicrobial Drug Products for Over-the-Counter (OTC) Human Use";

(L) Part 336, titled "Antiemetic Drug Products for Over-the-Counter (OTC) Human Use";

(M) Part 338, titled "Nighttime Sleep-aid Drug Products for Over-the-Counter (OTC) Human Use";

(N) Part 340, titled "Stimulant Drug Products for Over-the-Counter (OTC) Human Use";

(O) Part 341, titled "Cold, Cough, Allergy, Bronchodilator, and Anti-asthmatic Drug Products for Over-the-Counter (OTC) Human Use";

(P) Part 344, titled "Topical OTIC Drug Products for Over-the- Counter (OTC) Human Use";

(Q) Part 346, titled "Anorectal Drug Products for Over-the-Counter (OTC) Human Use";

(R) Part 348, titled "External Analgesic Drug Products for Over-the-Counter (OTC) Human Use";

(S) Part 349, titled "Ophthalmic Drug Products for Over-the-Counter (OTC) Human Use";

(T) Part 357, titled "Miscellaneous Internal Drug Products for Over-the-Counter (OTC) Human Use";

(U) Part 358, titled "Miscellaneous External Drug Products for Over-the-Counter (OTC) Human Use";

(V) Part 361, titled "Prescription Drugs for Human Use Generally Recognized as Safe and Effective and Not Misbranded: Drugs Used In Research"; and

(W) Part 369, titled "Interpretative Statements Re: Warnings on Drugs and Devices for

Over-the-Counter Sales."

(2) A manufacturer, repacker, own label distributor, jobber, or wholesaler or any person distributing over-the-counter drugs shall not market, promote or advertise the drugs in a manner inconsistent with or broader than that permitted by the over-the-counter tentative final monographs or final monographs in Title 21, Code of Federal Regulations, Parts 300 - 369.

(3) Copies are indexed and filed in the office of the Drugs and Medical Devices. Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756 and are available for inspection during normal working hours.

(o) Packaging, labeling, tests, and methods of assays for human antibiotic drugs.

(1) The department adopts by reference and will enforce Title 21, Code of Federal Regulations:

(A) Part 429, titled "Drugs Composed Wholly or Partly of Insulin";

(B) Part 430, titled "Antibiotic Drugs; General";

(C) Part 431, titled "Certification of Antibiotic Drugs";

(D) Part 432, titled "Packaging and Labeling of Antibiotic Drugs";

(E) Part 433, titled "Exemptions from Antibiotic Certification and Labeling Requirements";

(F) Part 436, titled "Tests and Methods of Assay of Antibiotic and Antibiotic-containing Drugs";

(G) Part 440, titled "Penicillin Antibiotic Drugs";

(H) Part 441, titled "Penem Antibiotic Drugs";

(I) Part 442, titled "Cepha Antibiotic Drugs";

(J) Part 444, titled "Oligosaccharide Antibiotic Drugs";

(K) Part 446, titled "Tetracycline Antibiotic Drugs";

(L) Part 448, titled "Peptide Antibiotic Drugs";

(M) Part 449, titled "Antifungal Antibiotic Drugs";

(N) Part 450, titled "Antitumor Antibiotic Drugs";

(O) Part 452, titled "Macrolide Antibiotic Drugs";

(P) Part 453, titled "Lincomycin Antibiotic Drugs";

(Q) Part 455, titled "Certain Other Antibiotic Drugs"; and

(R) Part 460, titled "Antibiotic Drugs Intended for Use in Laboratory Diagnosis of Disease."

(2) Copies are indexed and filed in the office of the Drugs and Medical Devices Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756 and are available for inspection during normal working hours.

(p) Distribution of drugs to flea markets.

(1) It is a prohibited act for flea markets to sell drugs unless the person selling the drug is authorized in writing to sell the drug at retail by the manufacturer of the drug or the manufacturer's authorized distributor.

(2) The authorization provided to the person selling drugs at a flea market shall state the person's name.

§229.254 Refusal, Revocation, or Suspension of License

(a) The commissioner may refuse an application for a license or may refuse to license a wholesale distributor of drugs, or may revoke or suspend the license if the commissioner determines after providing an opportunity for hearing that the applicant or licensee:

(1) has been convicted of a felony or misdemeanor that involves moral turpitude, including but not limited to the illegal use, sale, or transportation of intoxicating liquors, narcotic drugs, barbiturates, amphetamines, desoxyephedrine, their compounds or derivatives, or any other dangerous or habit-forming drugs;

(2) is an association, partnership, or corporation and any officer or management employee, partner, or any officer or director of the corporation has been convicted of a felony or misdemeanor that involves moral turpitude, including but not limited to the illegal use, sale, or transportation of intoxicating liquors, narcotic drugs, barbiturates, amphetamines; desoxyephedrine, their compounds or derivatives, or any other dangerous or habit-forming drugs;

(3) has violated any provisions of the Texas, Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431 or these sections;

(4) has failed to pay a license fee or an annual renewal fee for a license;

(5) has obtained or attempted to obtain a license by fraud or deception;

(6) has violated the Health and Safety Code, §431.021(1)(3), concerning the counterfeiting of a drug or the sale or holding for sale of a counterfeit drug;

(7) has violated the Health and Safety Code, Chapter 481 (Texas Controlled Substance Act), or the Health and Safety Code, Chapter 483 (Dangerous Drug Act); or

(8) has violated the rules of the director of the Department of Public Safety, including

responsibility for a significant discrepancy in the records that state law requires the applicant or licensee to maintain.

(b) Any hearings for the refusal, revocation, or suspension of a license are governed by the department's formal hearing procedures in Chapter 1 of this title (relating to Texas Board of Health) and the Administrative Procedure Act, Government Code, Chapter 2001.

(c) If the department suspends a license, the suspension shall remain in effect until the department determines that the reason for the suspension no longer exists. If the suspension overlaps a renewal date, the suspended license holder shall comply with the renewal procedures in §229.252(g) of this title (relating to Licensing Fee and Procedures); however, the department may choose not to renew the license until the department determines that the reason for suspension no longer exists.

(d) If the department revokes or does not renew a license, a person may reapply for a license by complying with the requirements and procedures in §229.252(a) and (c) of this title at the time of reapplication. The department may refuse to issue a license if the reason for revocation or non-renewal continues to exist.

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